THEORY AND METHODOLOGY OF INNOVATIVE EDUCATION DEVELOPMENT IN THE NATIONAL, EUROPEAN AND GLOBAL CONTEXTS

Katowice 2022

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Series of monographs
Faculty of Architecture,
Civil Engineering and Applied Arts
University of Technology, Katowice
Monograph 48

Publishing House of University of Technology, Katowice, 2022

Series of monographs Faculty of Architecture, Civil Engineering and Applied Arts, University of Technology, Katowice

Monograph · 48

ISBN 978-83-963977-1-3
DOI:10.54264/M003

Editorial compilation
Publishing House of University of Technology, Katowice
43 Rolna str. 43 40-555 Katowice, Poland
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INNOVATION SCIENTIFIC ACTIVITY OF MEDICAL COLLEGES AT U.S. UNIVERSITIES

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Abstract. The chapter covers the innovation scientific activity of medical colleges at U.S. Universities within engineering, design, and transfer of innovation products. Biomedical engineering deals with applying engineering principles and design concepts in the medical or biological field in the health care system for diagnostic, therapeutic, rehabilitation, and other purposes. Note that the transfer of innovative products of medical colleges at U.S. Universities is carried out within the implementation of the Bayh-Dole Act (1980) and amendments to it, adopted in the late 20th – early 21st centuries. Moreover, the problem of increasing the efficiency of transfer of products of innovation activity by developing innovation methods of assessing the commercial success of the proposed products has become relevant in current conditions.

Key words: innovation scientific activity, medical colleges, U.S. Universities, engineering, design, transfer.

Introduction

Medicine is clinical work and relationship building, teamwork, communication skills, research, innovation, publishing, and critical evaluation. Medical specialists are more likely to discover new clinical associations and syndromes and solve problems that medicine has never done before (Anand, 2014). So, the USA knows what innovations require: a continuous commitment to scientific research, a world-class workforce, and an economic environment. This rewards entrepreneurship and innovations. As the most dynamic and prosperous country globally, the United States has long benefited from policies and investments that promote innovation and, in turn, stimulate productivity and economic growth, foster U.S. trade, protect health and national security and defend the American dream (*Innovation: an American Imperative*, June 23, 2015).

Medical education as a whole and innovation activity of medical colleges at U.S. Universities, in particular, has become the issue of special interest of such foreign researchers as R. Asera, N. Al-Wardy, R. Atkinson, B. Barzansky, H. Beecher, F. Billings, F. Blaisdell, H. Weiskotten, N. Gevitz, K. DeZee, J. Dienstag, P. Jolly, R. Drake, E. Cordell, S. Lamb, K. Ludmerer, B. Murphy, A. Mortimer, B. Ogur, C. Pfeifer, S. Seifer, Ch. Smith, S. Smithson, T. Snyder, J. Takeuchi, C. Chapman, A. Chesney, P. Fallavollita, E. Fee, A. Flexner and others.

The Ukrainian scientific community has significant work on the development of higher education in the United States, including medical one: activity of adult education centres in the United States and Japan (N. Avsheniuk); development of the adult education system in the USA

(N. Bidiuk); training future teachers to work with gifted students in higher education institutions in the United States, Canada and the United Kingdom (M. Boichenko); alternative education in the USA (O. Zabolotna); use of U.S. experience in the organization of distance and blended learning in domestic universities (I. Zadorozhna); training of masters in higher education establishments of the USA (T. Kuchai); two-year nursing education in the USA (N. Lishchenko); theory and practice of corporate education in the United States (I. Lytovchenko); public administration of education in the United States (V. Luniachek); use of distance learning during the training of nurses-masters in the USA (I. Melnychuk); professional development of secondary school teachers in the systems of continuing pedagogical education in Great Britain, Canada, USA (N. Mukan); international activity as a factor of innovation development of U.S. Universities (O. Ogienko); management of scientific work in U.S. state universities (A. Sbruieva, M. Sbruiev, K. Shykhnenko); trends in the development of adult education in the United States and Canada (O. Terenko) and others. However, the innovation scientific activity of medical colleges at U.S. Universities still needs detailed study.

The research focuses on the innovation scientific activity of medical colleges at U.S. Universities within engineering, design, and transfer of innovation products.

Research results

Innovation scientific activity of medical colleges at U.S. Universities as a research problem

'A Strategy for American Innovation: Driving towards Sustainable Growth and Quality Jobs', published in 2009, identified promising areas for U.S. innovation activity in the nearest future.

According to the document, the increase in costs and the decrease in the quality of medical care were due to the inefficiency of the health care system. Using the latest information technologies in healthcare can increase efficiency, while broad reforms may involve businesses and individuals in innovation activity (*Executive office of…,* 2009).

The following promising areas of innovation activity were also identified:

- increase the use of advanced information technologies in the field of health care (mobile medical programs, electronic medical records, sensors for monitoring chronic diseases, etc.) to prevent medical errors, improve the quality of health care, modernize the health care system and reduce costs;
- renewing interest in biomedical research, in particular through targeted funding for research to detect genetic changes in various cancers, clinical trials of drugs to combat HIV/AIDS, identifying causes and treatments for autism, using DNA sequences to prevent and treat heart disease, lungs and blood;
- slowing the growth of health care expenditures through comprehensive health care reform and improving the quality of health care (*Executive office of…,* 2009).

In 2015, 'A Strategy for American Innovation reported that the Presidential Administration' was pursuing an additional policy to support an innovation ecosystem that benefits all Americans. In particular, thanks to it, American innovators have successfully implemented a project to create white blood cells that help kill cancers without damaging healthy cells (*National Economic…,* 2015).

The document identified the following prospects for U.S. innovation activity development:

- intellectual support for the regulation of innovation processes;
- service to the people;
- use of financial innovations following national priorities;
- strengthening the demand for American innovation strategy (*National Economic…,* 2015).

Also, according to the document 'Innovation: an American Imperative' (2015), the representatives of different fields declared their intention to act decisively and to urge Congress to renew the federal commitment to scientific discovery; make federal R&D tax credits permanent; reform the U.S. visa policy; take steps to simplify or eliminate costly and inefficient regulations;

stimulate further improvements in advanced manufacturing, etc. (*Innovation: an American Imperative*, June 23, 2015).

M. Sbruiev (Sbruiev, 2012a; 2012b; 2015) addressed the issue of development of scientific work in American Universities. Ukrainian researcher notes that 'the effectiveness of the management system of scientific work of a modern American public Universities is a complex, multifaceted function that depends on many external and internal variables' (Sbruiev, 2012b, p. 136). It can be considered as a matrix, which presents the areas of cooperation between the University and industry, society, and the state, which determine the economic and social components of efficiency, as well as the competencies of research administrators needed for the successful collaboration of scientists, administrators, politicians, educators and others (Sbruiev, 2012b, p. 136).

L. Fedulova focuses on the innovation University as an agent of change, which is 'an academic complex of collective entrepreneurship that dynamically and quickly adapts to the requirements of the external environment and operates in a competitive environment' (Fedulova, 2016, p. 163). This competitive environment includes domestic and foreign educational establishments that provide training and professional development of intellectuals; research centres that produce knowledge-intensive products; organizations providing educational and consulting services. Together, the outlined organizations also actively shape the structure and needs of the markets in which they operate (Fedulova, 2016, p. 163).

L. Fedulova emphasizes that in current conditions, the need to intensify innovation activity is relevant, which should cover two areas that complement each other: 1) implementation of innovative methods of managing higher education establishments, among which the top place is occupied by scientific management; 2) establishing partnerships with all actors not only in the national innovation system but also in the international innovation space, which includes such components as education, science and industry (Fedulova, 2016, p. 166).

The implementation of innovations requires companies to invest heavily in research, development, production and marketing and undergo a rigorous approval process through the FDA. The price of innovation is vast for those who invest in advanced technologies to develop medicine (Fargen et al., 2013).

As R. Atkinson and W. Blanpied rightly point out, the very emergence of research universities in the United States was once an innovation. Johns Hopkins University became the first American higher education establishment founded as a research university. After Johns Hopkins University, Clark University (1889), Stanford University (1891), and the University of Chicago (1892) began to consider themselves research establishments. At the turn of the 19th and 20th centuries, several public universities, including the Universities of California, Michigan, Wisconsin, Minnesota, and Illinois, also began to position themselves as leading research establishments (Atkinson, Blanpied, 2008).

The activities of American research universities were based on the following principles:

- meritocracy. It means management of persons with unique abilities and virtues, high intellectual abilities and qualifications, which meets the requirements of the scientific and technological revolution (Marutian, 2005, p. 335);
- organized scepticism. It deals with a willingness to take into account the most radical ideas, preferring the truth to the statement and inquisitive study - to the fact;
- creation of new knowledge; adherence to the principle that discoveries should be available to everyone, that those who make discoveries should not receive from this profit;
- system of expert assessment of the quality of the proposed research that needs funding;
- academic freedom and free research (Cole, 2016).

The mission of educational research universities 'involves a combination of three components of its activities: academic, scientific and social: the university must teach students, conduct research, serve society' (Sbruieva, 2010).

The development of medical education is due to the production of new knowledge and clinical approaches resulting from research. On the other hand, new research is driven by human diseases and medical problems, while the level of education and medical care is increasing through the involvement of students and trainees in the invention. The source of rapid discoveries and continuous improvement of medical education, which has led to significant medical progress, is the positive synergistic relationship between the main missions (Kerschner et al., 2018, p. 985) implemented by research universities.

The Ukrainian scientific and pedagogical discourse forms the idea of a research university as a higher education establishment 'with a high level of research activity, which has sufficient technological, resource base and intellectual potential for basic and applied research' (Sbruieva, 2021, p. 57).

Many of them have venture funds that complement external research funding with internal grants with the far-reaching goal of supporting promising young researchers (Sbruieva, 2010).

Necessary structural units within the medical colleges at U.S. universities are research centres and institutes. They were actively created at the beginning of the 21st century. According to W. Mallon and S. Bunton, research centres and institutes are organizational units with many goals, forms, sizes and characteristics (Mallon, Bunton, 2005, p. 1010).

Researchers distinguish two types of the following structural units:

- *the first type*, which accounts for about 85–90% of centres and institutions, is too simple. These structures play a limited but essential role in biomedical research enterprises. They must work with departments and other centres to achieve goals and missions successfully. They cannot independently control the teaching staff or have significant resources;
- *the second type*, 10–15% of the total, can be independent and play an essential role in the organization and management of the medical college and University. Such research centres and institutes are authoritative centres within the University, can influence scientists, report directly to the president of the University, have a large number. Directors of this type of centre can turn to important decision-makers who oversee financial matters and research policies (Mallon, Bunton, 2005, p. 1010).

W. Mellon and S. Bunton also note that these research centres and institutes make a vital contribution to the research mission of Universities. As researchers increasingly work to advance science and improve human health, medical colleges and Universities need to support the work of such units (Mallon, Bunton, 2005, p. 1010).

Moreover, W. Mellon adds that medical colleges differ in four aspects regarding the management of financial needs of research centres and institutes:

- *funding time.* The 'first dollar' is the initial funding, the allocation of small financial resources for a quick start to implementing innovative scientific ideas. The 'last dollar' is the search for external funding by research centres before the medical college considers financial investment;
- *funding request process.* It deals with the successive steps by which the academic staff submits an application for funds for the implementation of a project to the administration of the medical college;
- *decision-making structure.* It is related to official agreements, where funds are distributed not only between research centres and institutes but also other structural units;
- *funding culture.* It concerns common assumptions, professional values, and implicit rules related to organizational behaviour (Mallon, 2006).

We need to mention that a medical college is a kind of a business centre, as it aims to produce new knowledge and human resources for the health care industry. Therefore, the successful and productive activity of a modern medical college, which by its nature is innovative, largely depends on well-organized management. Governance, in turn, depends on economic, political, social factors and trends both in a given country and in the world.

O. Marmaza points out that 'innovation management arose based on achievements of various sciences (management, economics, psychology, pedagogy, sociology), which formed theories and accumulated positive experience of creative activity, scientific and technological progress, methods of improvement, activities. It is designed to ensure the implementation of strategic goals of the organization through innovation processes' (Marmaza, 2014, p. 311).

Innovation management belongs to the innovations of scientific and technological progress (Romanovskyi, 2010, p. 18). It deals with implementing management methods and techniques to create the most favourable conditions for the development of practical innovations. In addition, innovation management allows the educational establishment to adequately respond to external or internal challenges and attract employees at every level who are creatively involved in the development, creation of a new educational product and study the demand of the target audience (Andolfi, 2016, p. 65-67).

According to O. Romanovskyi, innovation management in education is a system of strategic management of innovation processes to study the main directions of educational, scientific, technical and industrial activities and justify a set of measures to implement innovation strategy. The tasks of innovation management include:

- development of plans and programs of innovation activity in the field of education;
- development and implementation of a unified innovation policy in the field of education;
- training of scientific and pedagogical specialists and providing all areas of educational activity;
- providing educational activity with the necessary resources (material, labour, financial, information);
- planning and selection of the best projects of educational innovations and control over its development;
- creation of particular groups of management and control over innovation activity in the field of education at all its stages (Romanovskyi, 2010, p.17).

According to the tasks, the main functions of innovation management are analytical and forecasting, planning, organization, control, regulation (Marmaza, 2014, p. 311).

The result of innovation management can be considered the expansion of innovation opportunities and strengthening the competitiveness of higher education. Such Universities, medical colleges attract creative personalities; they positively perceive creative ideas, accumulate innovation potential and develop innovation culture; support the image of organizations that constantly implement innovations, form the spirit of innovation activity (Marmaza, 2014, p. 315).

At the present stage of social development, no medical college can be developed without innovation management. Therefore, an important task is to monitor global educational and scientific innovations, society challenges, and cooperation with staff ready to innovate.

Another critical question for innovation scientific development is marketing. It is valuable for service or product providers in creating, communicating, and responding to the target market's challenges. Modern marketers start with customers, not products or services. They are more interested in building sustainable relationships than ensuring a single transaction. Their goal is to create a high level of customer satisfaction to return to the same supplier. Marketers have used many traditional methods, including marketing research, product or service design, distribution, pricing, advertising, promotional sales, and sales management. There is a need to add to these methods new ones related to innovative technologies and concepts to attract customers through messages and suggestions (Purcarea, 2019, p. 93-94). We believe that these principles and methods are also applied in the market of educational services, where, in our case, the suppliers are medical colleges.

Note that innovation is vital to ensure a modern, flexible education system that can stimulate innovation activity in the economy and society (OECD, 2016, p. 116).

The authors of the collective monograph 'Marketing Policy of Higher Education Establishments' believe that 'trends of globalization, intellectualization and informatization in the educational services market make adjustments to educational entities' behaviour, which raises the problem of theoretical understanding different levels. The development of competition in the provision of educational services actualizes the study of the processes of adaptation of higher education institutions to more stringent economic conditions, as well as issues of improving its competitiveness and quality of educational services as demand and viability' (Savytska et al., 2018, p. 6).

Medical Colleges and Universities have turned to market, hoping that by selling their services, student visits will increase. Moreover, fierce competition Universities encourages specific marketing strategies (Rudd, Mills, 2008, p. 43).

The Scrip website (https://thescript.zocdoc.com/) lists the main points to keep in mind when planning successful marketing strategies:

- marketing is not advertising, although advertising can play a significant role in a particular marketing strategy;
- marketing is an ongoing process. The strategy needs to be adapted to changes in the industry and the challenges of society;
- marketing is an investment. Not only should one plan to spend time and money on a particular marketing strategy, but one should also monitor the results to determine the return on investment and ensure a successful outcome;
- marketing is the relationship between a service provider or product and customers;
- marketing will be futile if one does not maintain the requirements (*12 Best Marketing*…, n.d.).

It is worth noting that these features of planning marketing strategies are practical not only for medical services or goods but also for medical education.

V. Purcarea emphasizes that the consumer usually receives certain information about the product through commercials in the media. However, important information still comes from recommendations or independent peer reviews (Purcarea, 2019, p. 94). For example, a potential student watches advertising videos on television, the Internet, social networks, but takes into account the feedback of graduates of the future place of medical education, especially if they are relatives and acquaintances, and appeals to the official rating of the educational establishments, specific expert assessments.

Analyzing marketing strategies, we state that the following are successful for medical colleges:

- creation and maintenance of an informative official website;
- creating and maintaining blogs;
- creation of the official page of a medical school in social networks, popular among potential students;
- involvement of mass media for comprehensive coverage of activities;
- electronic distribution of relevant information;
- creating an online profile on different platforms;
- use feedback from graduates of different years (*12 Best Marketing*…, n.d.).

In our research, it is also essential to turn to the model of the 'triple helix' of innovations, which deals with the relationship between university, industry and government, proposed by American scientist H. Etzkowitz and his colleague L. Leydesdorff from the University of Amsterdam, which focused on the networking of communications and expectations that changed the institutional arrangements between universities, industry and government (Etzkowitz, Leydesdorff, 2000) and applied this model to the study of knowledge-based economies (Cai, Etzkowitz, 2020).

H. Etzkowitz, analyzing the epistolary legacy by K. Compton, president of the Massachusetts Institute of Technology (1930–1948), found a positive interaction between the university, industry, and government to solve problems in the declining region. As a result, the 'triple helix' of innovations was created based on the observation, analysis and designation of specific innovation achievements (successful practices of regional innovations until the 1990s), in which economic growth was increasingly based on science and technology (Cai, Etzkowitz, 2020). The validity of this model was proven during the observation of the joint development of Stanford University and Silicon Valley (Zhou, Etzkowitz, 2021).

Thus, H. Etzkowitz and L. Leydesdorff note that, historically, the national organization of the innovation system has become necessary in determining competition. However, the reorganization of industrial sectors and nation states is due to new technologies (biotechnology, ICT, etc.). Further transformations can be analyzed from (neo)evolutionary mechanisms. University research will gradually occur in the 'laboratory' of such science-intensive network transitions (Etzkowitz, Leydesdorff, 2000).

According to researchers, in a knowledge-based society, the boundaries between public and private sectors, science and technology, universities and industry should gradually disappear, resulting in a system of interaction with planes of intersection, i.e. each industry, retaining its primary role and identity, can play the role of another in certain situations. So, the university plays an industry's role, supporting the creation of startups in incubation and acceleration projects (Leydesdorff, Etzkowitz, 1996).

This model implies that the university has the same status as the other two agents, i.e., an equal innovation participant. The 'triple helix' model of innovations identified three types: statist, laissez-faire, and balanced (Etzkowitz, Leydesdorff, 2000) – see table 1.1.

Table 1

Types of the models of the 'triple helix' of innovations

Type of the model of the 'triple helix' of innovations	Features	Stage in the U.S. history
Statist	The government controls the university and industry (even when university and industry representatives are part of the government); it plays a leading role in project development and providing resources for new initiatives	World War II
Laissez-faire	The university, industry and government are separate and independent of each other. Each participant in the relationship interacts with the other to a lesser extent through firm boundaries	The first postwar years
Balanced	It results from a dialectic between the laissez-faire model and practical needs. It creates an infrastructure of knowledge with interrelated institutional areas, each of which plays the role of the other and interacts with hybrid organizations that arise at the intersection	'Cold War'. The end of the 20th century – the beginning of the 21st century

Systematized by the authors based on (Etzkowitz, Leydesdorff, 2000; Cai, Etzkowitz, 2020)

Currently, the balanced type of the 'triple helix' of innovations applies to regional economic growth and entrepreneurship by understanding the interaction dynamics between university, industry, and government (Cai, Etzkowitz, 2020).

However, Y. Cai and H. Etzkowitz note that a pure model with a balanced interaction between the three spirals is unlikely to exist. At the same time, a muscular imbalance between spirals can deplete even the most successful innovation system (Cai, Etzkowitz, 2020).

As for Silicon Valley, J. Pique, J. Berbegal-Mirabent, and H. Etzkowitz argue that its' innovation ecosystem, as well as the role of the agents of the Triple helix, has changed over the last decade (from 2008 to 2018. – A. K. and M. B.)' (Pique et al., 2018).

The researchers have concluded that such changes are related to:

- launching acceleration programs as new participants in the ecosystem;
- cooperation of corporations with startups at an early stage;
- geographical expansion of Silicon Valley, which includes San Francisco;
- strengthening the interaction of universities with investment funds;
- growth of microcorporations due to lack of staff and fierce competition in the region (Pique et al., 2018).

Thus, the innovation scientific activity of medical colleges at U.S. Universities is satisfying but at the same time complex because it deals with strict government regulatory mechanisms, the peculiarities of funding and the specifics of innovations.

Engineering and design as types of innovation scientific activity of medical colleges at U. S. Universities

Considering engineering and design as types of innovation activity of medical colleges at U. S. Universities, we note that in this context, we will talk primarily about biomedical engineering that deals with applying engineering principles and design concepts in the medical or biological field in the health care system for diagnostic, therapeutic, rehabilitation, and other purposes.

It is indisputable that in the current conditions in the U.S. health care system and, consequently, medical education, the research area of innovations is actively developing. Because biomedical engineering involves the application of concepts, knowledge, and scientific approaches from a wide range of engineering disciplines to address specific health issues, the possibilities for collaboration between engineers and physicians are vast and diverse.

Before proceeding directly to consider biomedical engineering as a type of innovation activity of medical colleges at U. S. Universities, we consider clarifying the essence of this phenomenon. While A. Pacela defines bioengineering as a broad general term for the field as a whole (Pacela, 1990), most researchers believe that bioengineering is an activity related to biotechnology and genetic engineering, that is, the modification of animal or plant cells or parts of cells to improve plants or animals, or the development of new microorganisms for beneficial purposes (Bronzino, 2005; Enderle, Bronzino, 2012).

J. Enderle and J. Bronzino define the typical tasks of biomedical engineering:

- development of improved plant and animal species for food production;
- invention of new medical diagnostic tests for different diseases;
- production of synthetic vaccines from clone cells;
- bioecological engineering to protect people, animals, and plants from toxic substances and pollutants;
- study of protein-surface interaction;
- modelling the growth kinetics of yeast cells and hybridomas;
- research of the technology of immobilised enzymes;
- development of therapeutic proteins and monoclonal antibodies (Enderle, Bronzino, 2012).

Thus, the term 'biomedical engineering' is general. Biomedical engineers in their work apply the principles of electrical, chemical, optical, mechanical, and other types of engineering to understand, modify or control biological systems (humans and animals).

The field of biomedical engineering in modern conditions covers such areas as biomechanics; prosthetic devices and artificial organs; medical imaging; biomaterials; biotechnology; fabric engineering; neural engineering; biomedical instrumentation; bionanotechnology; physiological modelling; rehabilitation engineering; clinical engineering; biosensors; medical and bioinformatics; medical and biological analysis.

The main types of innovation activity of biomedical engineers include:

- research of new materials for implanted artificial organs;
- development of new diagnostic tools for blood analysis;
- creation of software for analysis of medical research data;
- analysis of the danger and effectiveness of medical devices;
- creation of new diagnostic imaging systems;
- design of telemetry systems for patient monitoring;
- design of biomedical sensors;
- creation of expert systems for diagnosis and treatment of diseases;
- design of closed control systems for drug administration;
- design of devices for sports medicine;
- development of new dental materials;
- development of means of communication for disabled people;
- study of the dynamics of pulmonary fluid;
- study of the biomechanics of the human body;
- creation of material for human skin replacement, etc. (Enderle, Bronzino, 2012).

This list is not exhaustive and depends primarily on the clinical/research environment in which the innovation activity occurs. At the same time, we will dwell on certain types of biomedical engineering in more detail.

One of the oldest innovations in biomedical engineering is prosthetics. It began to flourish after World War II when an unprecedented number of veterans returned home alive but disabled.

Prosthetics refers to any internal or external device that replaces lost parts or functions of the nervous system and can be orthopaedic or external controlled. Externally controlled devices can be powered from the body via myoelectricity or a separate power supply. The most innovative today is neural prosthetics.

Neural devices can be powered from the human body by electrical signals with the help of electrodes from an external source to peripheral muscle neurons and an external power source. Neural prostheses use functional electrical stimulation to restore sensory or motor functions. These prostheses can help people with the spinal cord or cervical injuries restore muscle and lower extremity function. Electrode stimulation should reach a threshold frequency to achieve tetany or smooth movement of muscle contraction. Stimulation below this frequency results in isolated twitching and muscle fatigue.

Note that neural prosthetics is a relatively common area of innovation in medical colleges at American Universities. In this context, the scientific article-review of neural prosthetic strategies, used in these establishments, was published by G. Loeb, Professor of Biomedical Engineering at the University of Southern California (Loeb, 2018).

The scientist considers a wide range of innovations in the field of neural prosthetics, namely:

- devices to control pain (transcutaneous electrical nerve stimulators, spinal cord stimulators, and other devices);
- Deep Brain Stimulation devices;
- cochlear implants;
- artificial eyes;
- devices that perform neuromuscular stimulation;
- devices that improve the function of the urinary system;
- devices that improve the function of the gastrointestinal tract;
- electrical drugs for autonomous modulation;
- devices to control epileptic strokes;
- devices that connect the brain to the computer;
- devices aimed at improving mental state (Loeb, 2018).

The next innovation of medical colleges at U.S. Universities is tissue engineering. It is a relatively new branch of biomedical engineering that produces biological tissue ex vivo or in vitro or introduces new advances to restore and grow existing tissues in vivo. In the case of ex vivo, bio-artificial tissues (consisting of both synthetic and natural materials) are used as an alternative to organ transplantation or are designed to study tissue behaviour in vitro. Some crucial issues in this area include cell isolation, cell organisation and function control, scaling up to full-fledged bio-artificial tissues, and biomaterial production.

Although the most well-known advances in tissue engineering have been made in epithelial tissues, researchers from medical colleges at U.S. Universities are currently conducting clinical trials to reconstruct cartilage, bone, nerve, and liver tissue. Transplants are used to treat all types of skin damage, including burns, bedsores, and diabetic ulcers. In addition, polymer tubes are implanted to promote nerve regeneration due to damage or disruption of the central and peripheral nervous system (Enderle, Bronzino, 2012).

Tissue engineering also involves the replacement of joints, including connective tissue repair and bone grafts. A bioreactor model is used within pancreatic and liver tissue. Bioreactors consist of many cells that receive reagents at the inlet and release a set of products at the outlet. Bioreactors are also used to produce blood cells from hematopoietic tissue. There are two types of bioreactor systems – hollow fibres and microcarrier-based systems.

An illustrative example of innovations in the field of tissue engineering is the activity of the Medical College of Wisconsin, which has many laboratories of tissue engineering, including:

- *Cardiovascular Regenerative Engineering Laboratory*. It develops substitutes for living tissues using regenerative engineering and biomedical nanotechnology approaches. The laboratory specialises in the development of living blood vessels, heart valves, vascular and cardiac patches, which can reconstruct, self-repair, and grow;
- *Computational Systems Biology Laboratory* uses an integrated experimental, computational approach to modelling to identify kinetic and molecular mechanisms and related biochemical drivers that regulate the functions of mitochondria, cells, and healthy tissues/organs, as well as to find out how failures in mitochondrial and cellular mechanisms leading to tissue/organ dysfunction and pathogenesis of various diseases;
- *OREC's Biomaterials & Histology Laboratory* assesses bone fillers and bone transplant substitutes, mechanisms and clinical applications of osteoinductive materials, and assesses materials for orthopaedic and vertebral devices;
- *Tissue Regenerative Engineering Laboratory* develops biofunctional tissues, providing advanced therapeutic opportunities for patients suffering from diseases such as the cleft palate and vascular disease (Medical College of Wisconsin. *Molecular & Cellular. Tissue Engineering Laboratories*, n.d.).

The following topical area of innovations in medical colleges at U.S. Universities is the study of stem cells. It has a powerful potential for radical changes in understanding and treating human diseases. For example, activating stem cells for tissue repair or direct isolation and transplantation is the basis of regenerative medicine.

Researchers use two different types of stem cells in their experimental work – embryonic and induced pluripotent ones. Embryonic stem cells come from embryos, mainly delivered by in vitro fertilisation clinics four to five days after fertilisation. At this point, the stem cells are either self-healing or fixed and differentiated. Self-healing or regeneration means that the stem cell will proliferate without commitment to development. In essence, the stem cell remains the stem cell. Differentiation is the expression of tissue or cell-specific genes. For most tissues of the human body, cells will be differentiated. However, in some cases, dynamic surgery is required, and, thus, the adult stem cell population is maintained for regeneration (Enderle, Bronzino, 2012).

In this context, the interdisciplinary doctoral program in Stem Cell Biology and Regenerative Medicine, launched by Stanford University School of Medicine and the world's first PhD program, deserves attention. It offers specialised training at the intersection of basic and clinical sciences, emphasising stem cell biology and regenerative medicine.

Within this program, third-level higher education students, under the guidance of experienced scientists, carry out a wide range of research to identify mechanisms that allow cells to transmit signals to each other (e.g., the relationship between stem cells and their niches). The identity of different cell types is established during development, from stem cells or by induced cell reprogramming, and how animals-model age. Educators also develop effective therapeutically relevant genome editing strategies, develop next-generation stem cell therapies, and direct stem cell differentiation into in vitro stem cell therapies. Educators use innovative technologies, including genome editing, single-cell transcription, chromatin analysis, microscopy, and advanced stem cell culture systems (Stanford Medicine. *About the Stanford Interdisciplinary PhD Program in Stem Cell and Regenerative Medicine,* n.d.).

In this aspect of innovations, Stanford University School of Medicine researches in the following main areas:

- *study of mature stem cells of tissues or organs.* Scientists expand their understanding of known stem cells that continue to function throughout life, so-called 'adult' stem cells, mature tissues or cells of organs that include hematopoietic, nervous, skin, and skeletal muscle stem cells. Research in this area also aims to understand the clinical application of these stem cells in areas such as regeneration of diseased or damaged organs and tissues;
- *studies of human embryonic and induced pluripotent stem cells.* Scientists study how embryonic cells are formed and how they differentiate to become different tissues in the body. Researchers have also been able to produce embryonic cells from mature cells;
- *research on new stem cell lines.* Scientists are studying how to create stem cells from specialised cells grown from the stem cell stage. This study includes the use of nuclear transfer technology and induced pluripotent stem cell technology to create new stem cell lines that serve as models for the study and treatment of diseases such as cancer, diabetes, cardiovascular disease, autoimmune diseases, and neurodegenerative disorders such as Alzheimer's, Parkinson's and Lou Gehrig's disease;
- *cancer stem cell research.* The scientists of this medical school have played a vital role in detecting and studying cancer stem cells, which are believed to underlie the destructive potential of cancer. Stanford University School of Medicine continues to be the global epicentre of cancer stem cell research. Scientists aim to conduct preclinical research to develop new therapeutic approaches to the destruction of cancer stem cells by transferring these results into clinical trials (Stanford Medicine. *Research,* n.d.).

Experienced and young scientists from the Keck Medical School of the University of Southern California are not left out of the study of stem cells. According to the website (https://keck.usc.edu/research/about-keck-school-of-medicine-research/), their findings represent fundamentally new knowledge in stem cell research and have led to crucial technological innovations. According to the journal Science, they entered the top 10 leading world achievements in 2010. In addition, two projects at the Keck Medical School of the University of Southern California – the California Project to Cure Blindness and Stem Cell Therapy for AIDS - received two prestigious awards from the Keck School of California's Institute of Regenerative Medicine (USC. *About Our Research,* n.d.).Genetic engineering is a powerful area of innovations for medical colleges at U.S. Universities. Along with the term 'genetic engineering' to denote the phenomenon of direct manipulation of body genes, scientists use the terms recombinant DNA, genetic modification/manipulation (G.M.), and more. Unlike traditional breeding, an indirect method of genetic manipulation, genetic engineering uses modern tools.

In particular, a team of scientists from the University of Illinois at the University of Chicago (Sh. Gao, J. Dai, D. Rehman) has developed software that allows researchers to more effectively identify gene regulators. The system uses a machine-learning algorithm to predict which transcription factors are likely to be active in individual cells.

Transcription factors refer to proteins that bind to DNA and control which genes are 'turned on' or 'turned off' inside a cell. These proteins are essential to biomedical researchers because understanding and manipulating these signals in the cell can effectively discover new treatments for many diseases. However, hundreds of transcription factors within human cells make it difficult to find the most active ones in different cell types that could be used as drug targets.

According to J. Rehman, a Professor of Medicine at the University Of Illinois School Of Medicine in Chicago, one of the problems in this area is that the same genes can be 'turned on' in one group of cells but 'turned off' in another group of cells within single organ. Understanding the activity of transcription factors in individual cells would allow researchers to study activity profiles in all major cell types of major organs, such as the heart, brain, or lungs (loc. cit. Carey, 2021).

Scientists have built the Bayesian inference transcription factor activity model based on the fundamental biological principle that differences in single-cell DNA sequencing profiles reflect the underlying states of transcription factor activity. This model has been tested in lung, heart, and brain tissue cells (Gao, Dai, Rehman, 2021).

According to Sh. Gao and others, the proposed approach identifies not only significant actions of transcription factors but also provides valuable information on critical mechanisms for regulating transcription factors. Furthermore, by providing such data for each transcription factor in a cell, the model can give researchers a good idea of which ones to look for when studying new drug targets to work on this cell type (Gao, Dai, Rehman, 2021).

Note that among the current areas of bioengineering research for employees and students of the University of Illinois at Chicago, a special place is occupied by scientific research on COVID-19.

Under the guidance of Associate Professor Zh. Peng, students T. Leong and Ch. Voletti created 'coarse-grained' models of two essential types of proteins: thorn proteins, which characterise the appearance of SARS-CoV-2 virus, and ACE2 receptor proteins in human cells, which allow attachment of coronavirus spikes. The proposed models provide a simplified idea of how molecules behave and interact and will be helpful to researchers in studying the complex processes that occur in the body when the coronavirus enters cells.

The researchers note that the developed models have helped confirm the scientific community's belief that the binding of thorn protein to the ACE2 receptor plays a critical role when the virus first enters human cells. The researchers added that they also have found that thorn protein is flexible and able to bend in a way that optimises its chances of breaking the ACE2 receptor (University of Illinois Chicago. *Bioengineers design coronavirus model*, n.d.).

To experiment, the researchers used molecular dynamics software called NAMD and VMD to simulate the physical motions of atoms and molecules that simulate both the ACE2 receptor, and the SARS-CoV-2 virus based on actual data to illustrate the process of endocytosis by which substances, such as a virus, get inside the cells.

Ch. Peng said it was difficult to simulate the process because it involved millions of atoms. However, the team solved the problem using the Theta supercomputer at the Argonne National Laboratory.

Although work on models of proteins, viruses, and cell membranes is still ongoing, the intermediate results of the study determine which part of the spike protein and which part of the ACE2 receptor bind to each other. Detection of these parts can help scientists develop antiviral drugs that would prevent the penetration of this thorn into human cells (University of Illinois Chicago. *Bioengineers design coronavirus model,* n.d.).

An important area of biomedical engineering in medical colleges at U.S. Universities is medical imaging. Medical imaging refers to methods and procedures to obtain reproductions of human body parts in the treatment and diagnostic process.

According to experts from the National Electrical Manufacturers Association, medical imaging has changed health care science. Innovation activities in medical imaging have led to faster and more accurate images, the procedures for which have become less invasive. If previously imaging was considered a tool for diagnosing diseases, it is also used to treat, control, and predict diseases in modern conditions. As a result, the use of medical imaging has become a necessity for almost all primary medical conditions and diseases. In addition, it is one of the standards of new medical care for diseases such as cancer, cardiovascular, trauma, neurological conditions, and more.

The concept of 'medical imaging' covers a wide range of methods of radiological imaging, such as radiography; photofluoroscopy; magnetic resonance imaging; ultrasound; endoscopy;

elastography; tactile image; thermography; functional imaging technologies for medical photography and nuclear medicine, such as positron emission tomography (PET). In addition, medical imaging is magnetoencephalography (MEG), electrocardiography (ECG), and electroencephalography (EEG) (*Medical Imaging,* n.d.).

Medical imaging also includes measurement and recording techniques that do not create 'images' but produce data often expressed in graphs or maps. These include electroencephalography (EEG), magnetoencephalography (MEG) and electrocardiography (ECG).

In current conditions, such methods of medical imaging are actively used as:

- *projection radiographs* – to detect bone fractures, pathological changes in the lungs and the diagnosis of certain types of colon cancer;
- *fluoroscopy* – to obtain real-time images of various internal parts and structures of the human body;
- *MRI* – to create two-dimensional images of the body and brain;
- *scintigraphy* – to capture two-dimensional images from the radiation released by the introduced radioisotopes, to identify areas of biological activity that may be associated with the disease;
- *positron emission tomography (PET)* – for the diagnosis or treatment of various pathologies using specific properties of isotopes and energy particles emitted from radioactive materials;
- *ultrasound* – to obtain images of the fetus, abdominal organs, heart, chest, muscles, tendons, arteries and veins for diagnostic purposes;
- *elastography* – to reflect the elastic properties of soft tissues in the body;
- *tactile imaging* – to create images of the prostate, chest, vagina, pelvic floor support structures and myofascial trigger points in the muscles by converting the sense of touch into digital images;
- *photoacoustic imaging* – to monitor tumour angiogenesis in vivo, blood oxygenation maps, functional brain imaging and skin melanoma detection;
- thermography methods – to detect breast tumours using programs such as telethermography, contact thermography and dynamic angiothermography;
- *tomography methods* – to obtain images of structures of thin areas of the body (CT, PET scan);
- *echocardiography* – to see the detailed structure of the heart, including chamber size, heart function, heart valves and pericardium (*Medical Imaging,* n.d.).

Note that such institutions carry out the innovative activities and training of specialists in medical imaging as J. Roy College and Lucille A. Carver University of Iowa, Medical College of the University of Arkansas, San Diego School of Medicine, and others.

In particular, Eric A. Hoffman, Professor of Radiology, Medicine and Biomedical Engineering at J. Roy College of Medicine and Lucille A. Carver of the University of Iowa created and headed the Advanced Laboratory of Pulmonary Physiological Imaging and the Iowa Comprehensive Center for Lung Imaging at Iowa University (University of Iowa Health Care. *Eric Hoffman, PhD,* n.d.).

Together with a group of researchers, he developed a dynamic spatial reconstructor. This one-of-a-kind C.T. scanner could collect up to 240 contiguous C.T. areas of the body every 1/60 second. He used advanced imaging techniques to study the basic physiology of respiration, focusing primarily on ventilation mechanisms, perfusion heterogeneity, and regional lung mechanics.

More recently, besides continuing basic physiological studies of the lungs, he created a combination of single- and multispectral multidetector line spiral C.T. imaging to objectively track human lung pathology and pathophysiology, focusing on inflammatory lung disease. The central element of APPIL is the Siemens SOMATOM Force computer scanner.

In 2018, Professor Hoffman received the Honored Researcher of the Academy of Radiology and Biomedical Imaging. He also received the 2013 John West Award for Outstanding Contribution to Functional Pulmonary Imaging from the International Seminar on Pulmonary Functional Imaging, the Joseph R. Rodarte Award for Scientific Achievement from the 2018 Alumni

Respiratory Structure and Functions Assembly of the American Thoracic Society and the Thoracic Society. The innovation activity of Professor E.A. Hoffman's Laboratory at the University of Iowa Medical College uses advanced imaging techniques to study normal and pathological lung physiology with specific areas of interest in inflammatory lung diseases, including asthma and environmental pathologies. In addition, APPIL serves as a radiological centre for numerous large-scale studies that use imaging to determine lung phenotype as part of research (University of Iowa Health Care. *Eric Hoffman, PhD,* n.d.).

Most of the innovative products in biomedical instrument engineering were created during the last 15-20 years. The introduction of biomedical devices revolutionised medicine and greatly facilitated the treatment of patients. The main principle of operation of biomedical devices is the conversion of signals found inside the body into electrical ones.

In current conditions, the main areas of research in the field of biomedical instrument engineering in medical colleges at U.S. Universities are:

- miniaturisation of traditional biomedical devices for the examination of individual cells or microscale tissues;
- adaptation of traditional biomedical devices for distribution and deployment outside the traditional care environment, such as at home and in resource-poor conditions (Berkeley Bioengineering. *Research. Bioinstrumentation,* n.d.).

Note that one of the leaders in biomedical engineering and design among medical colleges at U.S. Universities, which presents almost all of the areas outlined in this section, is Johns Hopkins University School of Medicine.

Next, we characterise the main areas of innovation activity of Johns Hopkins University School of Medicine, which serve as an illustrative example of a holistic system of innovation of research Universities in the field of bioengineering and design.

Biomedical Data Science includes the analysis of biomedical data arrays to identify features of the functioning of living systems. Academic and research programs in this area are focused on developing new data analysis technologies to clarify disease peculiarities and provide improved health care at a lower cost. For example, Johns Hopkins University School of Medicine students work with faculty to develop new cloud technologies and data analysis techniques to improve disease diagnosis and treatment. Moreover, students and teachers are developing innovative methods for analysing arrays of biomedical data that provide new knowledge about the functioning of living systems.

There are the following main areas of research:

- *computer science* (establishing interaction between computer science, mathematics, and biomedical engineering to improve computer technology to address a wide range of issues of personalised medicine);
- *machine learning and data science* (creation of high-performance software for extracting symbolic and ontological information from data sets using machine learning);
- *biomedical data* (integration of biomedical data with high-performance computing tools to analyse several terabytes of data used in modern tools of machine learning and artificial intelligence);
- *science as a service* (search for scientific solutions integrated into the software, development of new cloud technologies for the exchange of data sets and tools);
- *biomedical clouds* (creating essential resources to improve the quality of care) (Johns Hopkins School of Medicine. *Biomedical Data Science,* n.d.).

Computational medicine aims to improve healthcare by developing digital models of diseases, of the disease, personalisation of these models using patient data, and their use to improve the diagnosis and treatment of the disease. Specialists use these patient models to identify new risk biomarkers, predict disease progression, develop optimal treatments, and identify new drug targets. Students of the Medical School under study are developing new solutions in personalised medicine, building computational models in molecular biology, physiology, and anatomy of human health and diseases. Students and faculty are also innovators in developing and applying patient-specific quantitative models used in the clinic to understand, diagnose, and treat disease.

The main areas of research:

- *computational molecular medicine* means studying molecular networks, possible and impossible concentrations of biomolecules and their changes over time to make more informed clinical decisions;
- *computational physiological medicine* implies the development of disease models that combine information at different levels of biological organisation – from molecules and cells to tissues and organ systems – and the application of these models for patient care;
- *computational anatomical medicine* denotes the application of mathematical theory to model anatomical structures and their changes in health and disease, for example, identifying differences in brain shape and connections during neuropsychiatric diseases and neurodevelopmental disorders or classification of changes in heart shape and movement, characterising heart disease;
- *computational health* is the integration of biomedical signal processing, computational modelling, machine learning, and medical informatics to develop new approaches in personalised medicine using electronic medical records, physiological time series data, and genomics (Johns Hopkins School of Medicine. *Computational Medicine,* n.d.).

Genomics and systems biology focuses on making connections between information in the genome and the epigenome with the functions of biological systems, from cells to tissues and organs. At Johns Hopkins University School of Medicine, students and staff develop new computational and experimental methods for systematic genome analysis, building models with time and time scales, and using synthetic biology to develop new biomedical systems for human health. Students and teachers are also introducing new technologies to understand how interactions between molecules, cells, tissues, and organs support health and provoke disease.

The main areas of research in the field of genomics and systems biology include:

- *genome collection* develops new methods of assembling genomes that can reproduce genomes of any size using the latest sequencing technologies;
- *RNA transcriptomics and sequencing* means the development of computational methods for converting data into accurate indicators of gene activity and comparing gene expression in different conditions;
- *personal genomics and data modeling* indicates the development of new methods of large-scale integrated analysis of genomic, epigenomic, and transcriptomic data better to predict the impact of genetic variants on human health;
- *genomic and epigenomic engineering* means the use of new tools to edit the genome and epigenome and identify the links between the environment and genetics for the prevention and treatment of disease;
- *nanopore sequence* deals with the development of new technologies for determining the sequence and epigenetic modifications of individual DNA molecules for personalised medicine;
- *cell fate engineering* controls cell fate transitions by studying how genomes provide spatio-temporal control of gene expression;
- *synthetic biology* is the development, manufacture, and integration of new biological components, from individual genes to whole chromosomes and genomes (Johns Hopkins School of Medicine. *Genomics & Systems Biology,* n.d.).

Imaging & Medical Devices measure spatial and temporal distributions and signals at various scales (from molecules and cells to organs and entire populations). Combining mathematics, physics, and biological systems with the development of new devices and computational algorithms, the medical school academic and research programs focus on new technologies and intensive data analysis, including imaging technologies: optical, X-ray, CT, MRI, ultrasound, and molecular imaging; image analysis – image registration and reconstruction; gaining knowledge from image data; new medical devices – a wide range of diagnostic and therapeutic devices, due to clinical needs. The educational program covers mathematical foundations, physics of imaging technologies, design and development of devices based on clinical needs, and computational methods of image processing and analysis. In addition to knowledge of natural clinical systems and data, students study data analysis, modelling, and computer simulation techniques. Classroom experience classroom, research laboratory, and clinical settings connect education with practical, real-life cases.

Students and academic staff are introducing new imaging technologies to improve disease diagnosis and management of clinical procedures, researching the following main areas:

- *advanced biophotonics* means the use of innovative optical imaging technologies, including fluorescence and tomography microscopy and endoscopy, for early detection of the disease;
- *image analysis and registration* denote the use of mathematical models for strain alignment of multimodal images and information analysis to understand responses to the disease and treatment of Alzheimer's disease and other neurological disorders;
- *imaging algorithms* use high-precision physical models, reliable statistical methods, and machine learning to develop imaging algorithms, computational imaging and advanced image reconstruction and apply them during MRI, CT, and nuclear imaging;
- *new imaging systems* mean the development of new imaging technologies for optical endoscopy, molecular imaging, ultrasound, C.T., and MRI;
- *imaging-driven interventions* create new platforms and methods for image processing, such as cone-beam C.T., image recording, navigation, and robotics to use visualisation in high-precision interventions (Johns Hopkins School of Medicine. *Imaging & Medical Devices*, n.d.).

Immunoengineering uses the forces of the immune system to treat diseases such as cancer and promotes tissue regeneration and healing. The educational program involves the study of the studied phenomenon at the molecular, cellular, and systemic levels. Particular emphasis is placed on innovative materials and methods to engage the immune system to fight disease and promote tissue repair and healing. Students develop new biomaterials, vaccines, therapeutics, and systems to understand the function of immune cells and control their behaviour.

Students and academic staff research many areas, namely:

- *biomimetic materials* deal with the control of signals that regulate the reactions of immune cells on a macro-and nanoscale through biomimicry and improved design of materials;
- *regenerative immunology and ageing* means the creation of innovative platforms that modulate the innate and adaptive immune response to promote tissue regeneration and wound healing; study of the effects of ageing on the immune system and its functions in recovery and disease;
- *immuno-oncology* introduces innovative platforms that modulate immune responses to increase the effectiveness of vaccines, improve the delivery of drugs, and increase the effectiveness of cancer treatment;
- *Host Defense* denotes the development of new material and cellular therapy to correct the wrong immune response in case of autoimmune attacks and disorders or for augmentation – in case of liberation from foreign invaders;
- *system immunology and computational immunology* is the study of ways in which immune cells communicate with each other and tissues to perform their functions; creation of system models of cell and tissue functions to be used in experimental and translational studies; and the use of bioinformatics to improve the discovery of neoantigens;
- *molecular engineering* is the processing of natural proteins and creation of entirely new proteins as tools for understanding and manipulating the immune response; search for biotechnology to control the functions of immune cells (Johns Hopkins School of Medicine. *Immunoengineering*, n.d.).

Neuroengineering includes basic, experimental, computational, theoretical, and quantitative research to understand and strengthen the brain functions in health and disease on several spatio-temporal scales. The educational program aims to teach students to develop and apply new technologies to understand and treat neurological disorders. Students create tools to identify, control, improve, or block neural networks in specific spatial and temporal domains.

In addition to the academic component, students together with teachers introduce new technologies to modulate the functions of the nervous system to improve screening, diagnosis, prognosis, rehabilitation, and recovery and conduct research in the following main areas:

- *NeuroExperiments* mean development and use of experimental methods for measuring and manipulating the cognitive functions of the brain, including new methods in the system of neuroscience and brain mapping;
- *NeuroTech* is the development and implementation of tools for detection and control of the human brain and behaviour (neuromorphic engineering, intelligent agents, prosthetic devices, and robots);
- *NeuroData* imply the creation of intensive scientific opportunities for the brain, integrating neuroinformatics, computational neuroscience, and machine learning systems for analysis and modelling of neuroscience data sets of any size;
- *NeuroDiscovery* means discovering the basic principles of neural and connective coding, studying the internal coordinate system of the brain, and trying to decipher the unsurpassed ability of the brain to understand complex phenomena;
- *NeuroHealth* deals with improving, restoring, and increasing normal and impaired nerve function, focusing on diagnosing, diagnosing, and treating nervous system disorders (Johns Hopkins School of Medicine. *Neuroengineering,* n.d.).

Translational Cell & Tissue Engineering denotes the development and translation of innovation technologies to enhance or restore molecular, cellular, and tissue functions. According to the website of the educational establishment (https://www.bme.jhu.edu/research/research-areas/translational-cell-and-tissue-engineering/), Johns Hopkins University School of Medicine is a leader in translational cell and tissue engineering, which combines discovery, innovations, and translation through basic scientific, technical and clinical research. As a part of the educational program in translational cell and tissue engineering, students develop new techniques and biomaterials to guide cell behaviour and repair damaged tissues and organs.

The main areas of research in this area include:

- *molecular and cellular biotechnology* deals with the invention of new biological technologies to create new cellular microenvironments, targeted drug delivery platforms, and cell engineering both ex vivo and in vivo;
- *training materials* control signals that regulate cellular responses at the macro and nanoscale using high-performance platforms for synthesis and screening, tools for three-dimensional printing and design of functional materials;
- *cell therapy* means cell reprogramming as a living therapy for targeted treatment of diseases;
- *bioproduction* creates opportunities for the transmission of biological and cellular technologies for the new world bioeconomy;
- *computational regenerative engineering* denotes elucidation of the dynamic behaviour of cells integrated at different length scales, from molecules to tissues (Johns Hopkins School of Medicine. *Translational Cell & Tissue Engineering*, n.d.).

Thus, we can state that engineering and design are significant for the innovation scientific activity of medical colleges at U.S. Universities. According to the analysis of scientific references and websites of numerous medical colleges at U.S. Universities, as a rule, establishments focus on several areas of bioengineering due to the availability of appropriate logistical, laboratory, and clinical facilities. However, some establishments, such as Johns Hopkins University School of Medicine, are developing a wide range of areas in biomedical engineering. An essential feature of the innovation activity of the studied medical colleges is the combination of academic and research components in educational programs of all three levels (bachelor’s, master’s, and doctoral). These components provide simultaneous acquaintance with innovation achievements in biomedical engineering at medical colleges under the guidance of experienced academic staff.

Transfer of products of innovation scientific activity of medical colleges at U.S. Universities

The transfer of innovation products is carried out within the framework of implementing the provisions of the Bayh-Dole Act (1980) and its amendments adopted over the next forty years. According to the Report of General Accounting Office (*General Accounting Office*…, 1998), the first higher education establishments to form specialised units authorised to report and license inventions under the Bayh-Dole Act. At the end of the 20th century, the top ten research Universities in the United States had technology licensing offices or technology transfer offices.

As noted in the Report, the study identified the state of implementation of the Bayh-Dole Act among the U.S. research Universities, which included medical colleges, and found out the following four types of departments responsible for the transfer of innovation products:

- *centralised licensing office.* All activities are concentrated in one centralised unit. An example of such a unit is the Massachusetts Institute of Technology's licensing office, which coordinates innovations throughout the establishment, including the innovation developments of the Lincoln Laboratory, the Whitehead Biomedical Research Institute, and others;
- *decentralised licensing office.* Reporting and licensing activities are carried out by separate departments in different schools, departments, and other structural units of the University. For example, Johns Hopkins University has three licensing offices: one is for the School of Medicine, one is for the Applied Physics Laboratory, and another is for the rest of the University;
- *foundation.* An independent foundation conducts licensing activities established explicitly by the University for this purpose. The University may also have an office responsible for processing reports on implementing the Bayh-Dole Act. This scenario is most common among public Universities. An example of such an independent foundation is the Wisconsin Alumni Research Foundation;
- *contractor organisation.* Some universities enter into partial or complete licensing agreements. One of the largest contractors is the Research Corporation Technologies, Tucson, Arizona. However, this licensing management is gradually losing its popularity. In particular, many Michigan Universities with medical colleges initially used RCT services but later established centralised offices (*General Accounting Office*…, 1998).

In the context of technology transfer offices, there is a study by D. Weckowska on approaches to the commercialisation of products of innovation, namely: transaction-focused commercialisation practice and relations-focused commercialisation practice. According to the researcher, the proposed approaches to the commercialisation of innovation products are associated with different 'competence regimes', i.e. differences in understanding of a competent action and different 'worldviews', particularly, views on the innovation process (Weckowska, 2015).

The relations-focused approach to commercialisation practice focuses on building relationships between research, business, and University Technology Transfer Office managers. At the heart of this practice, there is the belief that a competent pursuit of commercialisation involves building and managing complex relationships between stakeholders in all commercialisation activities. Through relationships with researchers, technology transfer offices are aware of current research that can lead to commercial results. Potential licensees and investors are approached at an early stage. It is the opportunity to work with researchers on new technologies that stand out in marketing rather than the technology itself. Relationships with researchers and potential licensees become sources of information for technology transfer offices when deciding on a patent. For example, the information gathered in the process of interacting with potential licensees is used to manage patent claims in terms of what is the real value of what people want (Callon, 1998, p. 19), and, accordingly, the subjects involved in these processes shape the nature of the product and its value. Licenses or documents certifying intellectual property rights are seen as potential 'hooks for joint research', i.e. this is a starting point for complex long-term relationships between researchers and commercial organisations to create new knowledge jointly. The protection of intellectual property, the assessment of the invention's commercial potential, and the identification of licensees occur almost simultaneously. According to D. Weckowska, the relations-focused commercialisation practice is supported by implicit assumptions that the innovation process is an interactive one, that scientific discoveries must meet the needs and capabilities of the industry, and that bilateral communication between University and industry and the collaboration of market experts and research and development are crucial (Weckowska, 2015). The same assumptions underlie the interactive or 'coherent' innovation model described by R. Rothwell (Rothwell, 1994).

The transaction-focused approach to commercialisation is characterised by interpreting research results as marketable products and focuses on implementing such intellectual property transactions as sales and licensing. This approach is concentrated on the belief that a competent study of commercialisation entails commodifying scientific knowledge and the successful sale and licensing of intellectual property. According to D. Weckowska, managers of technology transfer offices who follow this practice emphasise the importance of skills to sell the idea to the outside world. As soon as a researcher discloses research results that can be commercialised, the technology transfer office 'produces' it, securing intellectual property rights. The product (e.g. patented technology) is then sold to potential licensees and investors. Commercial organisations are perceived as 'buyers' and are not approached until the product is considered 'ready', as it is believed that the technology transfer office must fully understand the economics of the new product and its scalability to be able to give potential licensees complete picture so that they have fewer questions and fewer reasons to say no. Licensing or resale of innovation products is considered an end in itself. This approach is linear because specific measures for commercialisation (patenting, marketing, negotiations, concluding agreements) are performed consistently. This position is characteristic of an early innovation model or scientific impetus by B. Godin (Godin, 2006). Thus, the transaction-focused approach to commercialisation is based on a linear understanding of the innovation process.

The researcher emphasises that the transaction-focused commercialisation practice is limited, so managers of technology transfer offices who use this approach should know this fact and invest in developing different ways to identify opportunities for commercialisation, intellectual property management and cooperation with commercial organisations and researchers (Weckowska, 2015).

Thus, we can state that the approach to commercialising innovation products, focused on relationships, is more effective. After all, technology transfer offices manage the use of university research results for for-profit and public benefit, providing support in patenting, licensing, and other aspects of innovation commercialisation.

In order to reflect the activity features of these structural units, we consider it appropriate to refer to the experience of organising technology transfer in some establishments of higher medical education. Therefore, both decentralised technology transfer offices regulate this process, not in the whole University, but directly in the medical colleges at U.S. Universities, and centralised ones were selected for the case analysis.

An example of a decentralised office is the Office of Technological Development of the Medical College of Wisconsin. Its mission is to support and train medical college faculty, doctoral students, interns, students and staff. Moreover, the Office of Technology Development focuses on the transfer of technology from research and clinical practice to commercial products that benefit the Medical College of Wisconsin, the local community and the general public. The Office of Technological Development is a division of the Office of Research and reports to the Deputy Dean for Research at the Medical College of Wisconsin. In addition, the Office of Technology Development engages inventors and internal and external stakeholders to 'bring patents to patients' (*Medical College of Wisconsin. Office of Technology Development*, n.d.).

The Office of Technological Development is responsible for managing and commercialising inventions, newly developed software, and other intellectual property assets of the Medical College of Wisconsin and promoting these assets from patents to patients. Employees of the specified structural unit identify, assess and protect intellectual property and then license it to well-known companies or startups, which then develop these new technologies into commercial products (*Medical College of Wisconsin. Office of Technology Development*, n.d.).

The Medical College of Wisconsin is a corporation that specialises in patient care, education, research, and community engagement, and where new knowledge is constantly generated, developed, or otherwise put into practice, the institution maintains best research practices, encouraging the expression of knowledge in the form of patented inventions, new research tools, copyrighted documents, books and software, as well as other work related to educational activities. Besides, the Medical College of Wisconsin seeks to translate and transfer this knowledge in forms that may be useful to the public (*Medical College of Wisconsin. Office of Technology Development*, n.d.).

Technology development and commercialisation priorities correspond to the mission of the researched establishment of higher medical education, support entrepreneurship, and promote research cooperation with other academic establishments and industries. The description of the corporate establishment policy, in the section 'Patent and Copyright', contains instructions on the process of technology transfer and related rights and responsibilities.

Note that the process of bringing technologies to market is often repetitive, but for many health technologies that need significant investment and regulatory approval, the timing is usually generalised.

Starting with the invention submitted to the Office of Technological Development by the inventors, the unit assesses the market potential of products and services using its internal experience and seeking confidential feedback from external experts with experience in intellectual property law, business and product development in the field of medical technology. The staff of the Technology Development Office then submits the results of the technical analysis together with their decision to preserve intellectual property rights and invest resources in protection and licensing, return rights to inventors or report that the discovered technology does not provide enough data to assess market prospects adequately.

Considering the activities of the Office of Technology Transfer and Intellectual Property Development of Tulane University, we note that this structural unit is an example of a centralised office that transfers products of innovation not only to the Medical School, which is part of it but also the School of Science and Technology, the School of Public Health and Tropical Medicine and the School of Law.

According to Tulane University Office of Technology Transfer and Intellectual Property, its main functions include:

- promoting cutting-edge research to the broader community;
- informing external users about the development and implications of research;
- tracking how the Tulane University innovation products are used for the most significant public benefit.

Unlike other higher education research institutions, where technology transfer is seen simply as a potential source of income, Tulane University considers the transfer to be a means of achieving significant challenges in education, research and services *(Office of Technology Transfer and Intellectual Property Development. Technology Transfer at Tulane University: History and Mission*, n.d.).

The office website (https://ott.tulane.edu/home/about-us/) contains information on the crucial achievements in transferring innovation products at Tulane University.

Peptide chemistry. Research in peptide chemistry has proven its effectiveness: three pharmaceutical peptides discovered by researchers have been approved by regulatory authorities and are used to treat patients for various indications.

Triptorelin is used to treat hormone-responsive cancers, such as prostate or breast cancer, and assisted reproduction. As of 2007, triptorelin was registered in more than 60 countries, including 25 in Europe. Triptorelin was first developed in the laboratory of Dr A. Shelley of Tulane University School of Medicine. Dr A. Shelley currently works at the University of Miami (Florida) and the South Florida Foundation for Research and Education.

Lanreotide is a drug used to treat acromegaly and symptoms caused by neuroendocrine tumours, especially carcinoid syndrome. It is a long-acting analogue of somatostatin. It was developed by Dr D. Coy, a researcher at Tulane University School of Medicine.

Cetrorelix acetate is a synthetic decapeptide used to treat hormone-sensitive prostate and breast cancer in pre-/perimenopausal women and treat some benign gynaecological diseases. Cetrorelix is also used in ancillary reproduction. Cetrorelix was launched in Europe in 1999, in the United States in 2001 and in Japan in 2006 and approved in more than 90 countries. The drug was developed in the laboratory of Dr A. Shelley.

Tulane University School of Medicine researchers found that many peptides are currently undergoing clinical trials. The first, for the treatment of ovarian and endometrial cancer, was developed by Dr A. Shelley. The second, for pain control, was developed by Dr J. Zadina. The third peptide is clinically tested as an anti-influenza drug. This compound and many other promising related peptides were developed by Dr R. Harry (*Office of Technology Transfer and Intellectual Property Development. Technology Transfer at Tulane University: History and Mission*, n.d.).

Diagnosis of infectious diseases. Tulane University has made significant progress in diagnosis by developing a high-precision test for Lyme disease. The veterinary version of this diagnostic technology is included in one of the most widely used animal tests in the United States.

Vaccines against infectious diseases. The International Non-Profit Organization PATH continues to study a vaccine adjuvant developed in the laboratory of Dr J. Clements of Tulane University School of Medicine for use in children health in developing countries (*PATH. Development and Relief Services*, n.d.). If successful, this vaccine will play an essential role in reducing diarrheal diseases caused by enterotoxigenic Escherichia coli, a major cause of disease and death in developing countries. Another charity organisation assesses the use of this adjuvant in the polio vaccine and for use in children in developing countries.

Medical products. Essential innovation products at Tulane University in this area are a catheter to improve the placement of ventricular pacemakers, invented by Dr J. Pigott from the School of Medicine, and an obstetric device that clamps and cuts the umbilical cord in a motion. The device was developed to improve health in developing countries, where traditional childbirth procedures often involve unsanitary conditions that lead to frequent illness and death among infants and mothers. Undergraduate students developed the obstetric device under W. Ketman in cooperation with Dr D. Rice (*Office of Technology Transfer and Intellectual Property Development. Technology Transfer at Tulane University: History and Mission*, n.d.).

Columbia Transfer Ventures (CTV) is a higher education division that supports many initiatives in technology development, entrepreneurship, external collaboration, and commercially-oriented multidisciplinary technology innovations. CTV primary mission is to facilitate the transfer of inventions from academic research laboratories to the market for the benefit of society at the local, national and global levels. According to the Columbia Technology Ventures website (https://techventures.columbia.edu/about-ctv/technology-transfer-columbia), it manages more than 400 disclosures, 100 licensing agreements and 20-30 new startups each year with support for innovation products, attracting more than 750 inventors on the campuses of Columbia University. CTV currently has more than 1,500 patented assets available for licensing in research areas such as biotechnology, IT, devices, big data, nanotechnology etc. (*Columbia Technology Ventures. Technology Transfer at Columbia*, n.d.).

Columbia University Technology Transfer Office has extensive experience creating and supporting technology initiatives that enable promising technologies to quickly overcome the ‘valley of death’ and enter the market as quickly and successfully as possible. Many of these initiatives are multi-institutional and require broad collaboration with partner universities and their technology transfer offices. Several CTV organisations have played essential roles in building partnerships, including the PowerBridgeNY clean energy proof-of-concept centre, the NYC Media Lab, and Columbia Biomedical Technology Accelerator. In addition, the Resource Translational Therapeutics (TRx) was established in 2016 in collaboration with the Irving Institute for Clinical and Translational Research and the Clinical Trials Office to promote new medicines from the laboratory through commercialisation to clinical implementation (*Columbia Technology Ventures. Technology Transfer at Columbia*, n.d.).

Columbia University Technology Transfer Office is supported by 45 full-time staff and more than 30 CTV fellows, providing broad support to the Columbia community and other stakeholders in marketing, law (patents, contracts, etc.), business, and administration. The CTV Executive-in-Residence program also attracts experienced industry leaders, serial producers, and investors to the Columbia University campus to support academic staff and students *(Columbia Technology Ventures. Technology Transfer at Columbia,* n.d.).

CTV offers a range of services to faculty, students and staff at Columbia University:

- filing a patent application and managing innovation products;
- marketing of innovation technologies;
- concluding license agreements on innovation technologies;
- concluding agreements on the transfer of materials and data;
- concluding confidentiality agreements;
- express licensing' of software;
- inter-institutional cooperation;
- opportunity to participate in the Columbia Women Inventor Network (Columbia WIN), etc.

Columbia University Technology Transfer Office attracts industry and investors to:

- concluding license agreements;
- concluding sponsored research agreements;
- concluding agreements on the transfer of materials and data;
- concluding confidentiality agreements;
- meetings with scientists on campus;
- expanding investment opportunities;
- empowerment of mentoring;
- presentation of innovation products to potential investors (pitch events);
- publishing newsletters on available innovative technologies, etc. *(Columbia Technology Ventures. Technology Transfer at Columbia*, n.d.).

The Nova Southeastern University Technology Transfer Office reports to the Office of Research and Technology Transfer, which reports to the Department of Translational Research and Economic Development, which supports the research infrastructure of the South-Eastern University of Nova. In addition to the Technology Transfer Office, the Office of Research and Technology Transfer oversees the Office of Sponsored Programs, Clinical Research, and the Grant Writing Laboratory.

The purpose of the technology transfer office is to transfer research from academic laboratories to society. The above-mentioned structural subdivision of the Nova Southeastern University seeks to commercialise the University innovations for the outside world to maximise the positive social impact and strengthen the economy. Among many existing commercialisation options, the technology transfer office helps choose the one that will help achieve the best results that benefit the inventor, investor and university (*NSU Florida. Office of technology transfer. About us*, n.d.).

The scope of the technology transfer office includes the protection and management of intellectual property, compliance with federal regulations, assistance in filling out application forms and contracts, assessment and marketing of inventions, commercialisation of innovations and management of revenues from this commercialisation activity. Moreover, this office also promotes the formation of subsidiary enterprises of the University, promotes cooperation with strategic corporate partners, increases the efficiency of innovative educational activities and creates economic value for the benefit of society (*NSU Florida. Office of technology transfer. About us,* n.d.).

The Technology Transfer Office of the Nova Southeastern University (https://www.nova.edu/ott/researchers-inventors/process.html) in the section 'Technology Transfer

Process' provides a detailed description of it, covering many stages, to be completed, which takes several years.

1. *Research and invention.* The first step in commercialising any University invention is research and discoveries made by the inventor (inventors). This crucial initial step is carried out by teachers, staff and students in research laboratories in a wide range of disciplines.

2. *Disclosure of inventions.* Suppose faculty, staff, or students believe that their research has led to an invention and potential commercial value. In that case, they must complete the invention and disclosure form at the Technology Transfer Office. This form is a confidential internal document for declaring an invention, which allows the Technology Transfer Office to initiate the appropriate process. The Technology Transfer Office cannot initiate an assessment of any invention and take the next necessary steps related to the technology transfer process until the inventors have received a standard form of invention and disclosure. However, the technology transfer office managers warn the inventors that the proposed form is only an internal document and does not offer legal protection for intellectual property (*NSU Florida. Office of technology transfer. Process of Technology Transfer,* n.d.).

3. *Assessment of the product of innovation activity by the Technology Transfer Office.* Office staff assess the invention using the information provided by the inventors through the invention and disclosure. Moreover, such criteria as novelty, patentability, and competitive advantage over similar existing technologies, future commercial value and various other factors based on which office managers decide whether the invention of the Nova Southeastern University is suitable for the protection of intellectual property and future development is considered.

4. *Protection of intellectual property rights.* After the invention is initially assessed and a decision is made to invest the resources of the Nova Southeastern University to protect its intellectual property, the staff of the technology transfer office begins to work with an external patent attorney to submit the relevant documents. The first step is to file a preliminary application with the U.S. Patent and Trademark Office. The next step is to apply for a Patent Cooperation Treaty application within 12 months of the previous application. Finally, the Technology Transfer Office staff advises and informs the inventors about all steps to protect intellectual property rights.

5. *Commercialisation.* After protecting intellectual property rights, the staff of the Technology Transfer Office develops a plan for marketing and the commercialisation of technology. The Technology Transfer Office is working with external corporate partners and inventors at Nova Southeastern University to determine the path of commercialisation that is ideal for each technology, as there are several ways to commercialise, and which path is most appropriate will depend on many factors, such as stage development of the invention, plans of the inventors and commercial demand for the technology. The final decision on commercialisation and identification of corporate co-authors can be made only after consultation with the inventors.

6. *Income management.* Once the external corporate partner starts making a profit by commercialising the technology acquired at Nova Southeastern University, a predetermined portion will be distributed to the designated higher education establishment. Unless all parties agree to another income distribution plan in the written agreement, the inventors and the University receive 50% of the 'net income'. In the Employee Policy Manual, one can find detailed information on income distribution in the Important Documents section of the above-mentioned Technology Transfer Office website (*NSU Florida. Office of technology transfer. Process of Technology Transfer*, n.d.).

According to the analysis of the Technology Transfer Office of Nova Southeastern University, cooperation with potential partners in the field of transfer of innovation products can be structured in different ways. Each invention/technology is unique; transfer agreements are developed on a case-by-case basis. The types of agreements used by the Technology Transfer Office of Nova Southeastern University are listed below.

License Agreement. It gives the company the right to commercialise intellectual property. In addition, the license agreement outlines revenue sharing plans, legal details, and product development deadlines.

Optional agreement. It allows the industry partner to assess the technology and its cost before finally licensing and paying the license fee. Its signing does not provide the right to commercialise the technology. Such an agreement provides only a limited time to develop innovation technology further and ultimately make a more informed decision to enter into a license agreement. After internal research and assessment, the company can use the option and sign a license agreement.

Sponsored research agreements. The industry can sponsor all or part of Nova Southeastern University research project relevant to their specific area of interest. So, the company can participate in the project early and prioritise licensing the inventions that may arise within this sponsored research project. The agreement sets out details such as intellectual property rights, the scope of work, the duration of the project and the amount of financial support from the company.

Alliance for Industrial and Academic Research. This agreement will be implemented if the researchers hired by the the company are interested in collaborating with one of the researchers from Nova Southeastern University. Before initiating such a joint research project between industry and University, it is necessary to agree on research cooperation, which will contain information on the legal conditions, each participant contribution, intellectual property rights and other relevant details. The most apparent difference between this type of agreement and the sponsored research agreement is the company significant intellectual and scientific contribution (*NSU Florida. Office of technology transfer. Types of Agreements,* n.d.).

Note that the Technology Transfer Office makes requirements not only for products of innovation activity that may be subject to commercialisation but also for partner organisations that must meet many criteria:

- the management team must have previous experience in the relevant field(s);
- before the conclusion of the agreement, the partner the organisation must submit a business plan that defines the development strategy of the invention;
- the partner organisation must provide some evidence of its ability to provide adequate financial support and employ the skilled labour needed to develop, manufacture and commercialise the technology;

The partner organisation must demonstrate its ability to achieve short-term and long-term development goals (*NSU Florida. Office of technology transfer. Criteria for Licensing NSU Technologies,* n.d.).

However, as mentioned above, only an invention that has proven its patentability will be commercialised: it must be new, unique and valuable. At the stage of disclosure of the invention, managers of the Technology Transfer Office pay attention to the following characteristics: the invention meets the need or solves an existing problem; the inventor has good scientific data or a the working prototype of the device, etc. (*NSU Florida. Office of technology transfer. For Researchers and Inventors*, n.d.).

In this context, we emphasise that deciding on the appropriateness of the transfer of an innovative product is a responsible step that requires employees of the Technology Transfer Office to have innovative methods of assessing the commercial success of the proposed products. Furthermore, it is undeniable that the use of effective mechanisms for assessing the products of innovation of University staff helps increase the rate of disclosure of inventions, reduce staff dissatisfaction and minimises time for discussions on the feasibility of selecting a product of innovation.

One such tool is the Invention Assessment Tool, which is used in business and can be adapted to the conditions of the educational establishment. Indicative in this context is the experience of the University of Kansas Medical Center Technology Transfer Office, whose staff began assessing various diagnostic tools in the fall of 2005 to improve licensing and commercialization procedures and speed up the verification process of inventions and discoveries that had commercial potential. This search resulted in the adaptation of the VentureQuest assessment tool uses a simple assessment scale that minimises ambiguous responses. Thus, the Innovation Assessment Tool, adapted by the University of Kansas Technology Transfer Office, provides objective, pragmatic feedback, identifying strengths and weaknesses of the proposed invention to reduce risk and achieve tremendous success in commercialisation. The specified assessment tool contains 31 parameters by which the development is assessed, grouped into the following sections:

- *assessment of an inventor*. The researcher supports commercialisation; the researcher has previous patents/copyrights; the researcher has published numerous peer-reviewed articles; the researcher has experience working with commercial partners; the a researcher has experience in the field of technology transfer; the inventor has constant funding for research;
- *protection of intellectual property rights*. It includes a high probability of obtaining international intellectual property rights; the number of barriers to the development of the invention; 100 per cent ownership; absence of legal obstacles; limited existing intellectual property competition rights; probability of protection of intellectual property rights (patents); probability of protection of intellectual property rights (copyright);
- *characteristics of a product/service*. It includes invention implementation; strong technical differentiation; lack of apparent technical obsolescence; several separate products/services; lack of state regulation; lack of additional research and development;
- *market characteristics*. It deals with recognised, established market; active growth potential of the target market; lack of competition; offer high value for customers; stable competitive advantage;
- *commercialization strategy*. It includes many ways to commercialise; continuity of income flow; potential for high gross profit at a competitive price;
- importance for the University of Kansas Medical Center is high potential for research funding; high potential for licensing; it improves the image/impact of the University of Kansas Medical Center; well-known potential employees or license.

According to K. Price, R. Houston, and A. Meyers, this assessment methodology helped increase the efficiency and objectivity of the process of commercialising innovation products at the University of Kansas by assessing only those characteristics that are critical to the achievement of strategic goals and objectives; faster and earlier assessments of commercialisation, which document the reasons that hinder the advancement of technology; reduction of the assessment time of each technology to 80%; conducting interactive discussions with business-oriented researchers; focusing on communities/differences in ratings with an emphasis on strengths, weaknesses and potential aspects of technology; reduction of subjectivity in assessment; allocating resources to support the most promising technologies (Price et al., 2008).

So, we can state that the technology transfer offices of U.S. Universities, including medical colleges, license, patent, and commercialise the results of innovation scientific activity of medical colleges based on modern innovative methods of selecting patentable innovative products and careful selection of partner organisations for promotion.

Conclusions

So, the research highlights the areas of innovation scientific activity of medical colleges at U.S. Universities, particularly engineering and design, technology transfer.

Medical or biomedical engineering, which involves the application of medical and biological engineering principles and concepts in the health care system for diagnostic, therapeutic, rehabilitation and other purposes, is considered in the context of the characterization of innovation in medical colleges.

There are the following products of innovation scientific activity: biomechanics; prosthetic devices and artificial organs; medical imaging; biomaterials; biotechnology; fabric engineering; neural engineering; biomedical instrumentation; bionanotechnology; physiological modelling; rehabilitation engineering; clinical engineering; biosensors; medical and bioinformatics; medical and biological analysis.

The paper presents an example of innovation activity in tissue engineering of the Medical College of Wisconsin, which has many tissue engineering laboratories, including Cardiovascular Regenerative Engineering Laboratory, Computational Systems Biology Laboratory, OREC's

Biomaterials & Histology Laboratory, and Tissue Regenerative Engineering Laboratory. The products of such innovation activity have become substitutes for living tissues (blood vessels, heart valves, vascular and cardiac patches that can reconstruct, self-healing and growth), bone fillers and bone graft substitutes, etc.

Moreover, there is the focus on the world first interdisciplinary doctoral program in stem cell biology and regenerative medicine, introduced by Stanford University School of Medicine. Under this program, third-level higher education students carry out a wide range of research under the guidance of experienced scientists: develop next-generation stem cell therapy, investigate the inherited basis of complex human diseases by introducing genetic variants into cultured stem cells, and direct differentiation valuable cell types.

The directions of stem cell research at Stanford University School of Medicine are covered: research of mature stem cells of tissues or organs; study of human embryonic and induced pluripotent stem cells; research of new stem cell lines; study of cancer stem cells, etc.

An important area of biomedical engineering in medical colleges at U.S. Universities is medical imaging, namely methods and procedures aimed at obtaining reproductions of parts of the human body in the treatment and diagnostic process.

An example of a holistic system of innovation scientific activity in the field of bioengineering and design is the activity of Johns Hopkins University School of Medicine, which includes components such as biomedical data (computational science, machine learning and data science, biomedical data, science as a service, biomedical clouds); computational medicine (computational molecular medicine, computational physiological medicine, computational anatomical medicine, computational health care); genomics and systems biology (genome collection, transcriptomics and RNA sequencing, personal genomics and data modeling, genomic and epigenomic engineering, nanopore sequence, cell fate engineering, synthetic biology); visualization and medical devices (advanced biophotonics, image analysis and registration, imaging algorithms, new imaging systems, imaging-controlled interventions); immune engineering (biomimetic materials, regenerative immunology and aging, immuno-oncology, host protection, system immunology and computational immunology, molecular engineering); neuroengineering (neuroexperiments, neurodata, neurodiscovery, neurohealth); translational cell and tissue engineering (molecular and cellular biotechnology, cell therapy, bioproduction, computational regenerative engineering).

The transfer of innovation products of medical colleges at U.S. Universities is carried out within the implementation of the Bayh-Dole Act (1980) and amendments to it, adopted in the late 20^{th} – early 21^{st} centuries. The main types of structural units responsible for the transfer of innovation products are centralized office (responsible for technology transfer throughout the University, e.g. Massachusetts Institute of Technology Technology Licensing Office); decentralized office (responsible for technology transfer within a separate structural unit, e.g. Johns Hopkins University has three technology transfer offices: for School of Medicine, applied physics laboratory and the rest of the University); foundation (an independent agency created explicitly by the University to conduct licensing activities, e.g. Wisconsin Alumni Research Foundation); contractor organization (provides for the conclusion of agreements on partial or complete licensing activities, e.g. one of the largest contractors is the Technology Research Corporation, Tucson, Arizona). At the present stage of the development of innovation activity of medical colleges at U.S. Universities, the most common are the first two types – centralized and decentralized offices.

It is determined that in current conditions, the issue of increasing the efficiency of transfer of products of innovation activity by developing innovative methods of assessing the commercial success of the proposed products has become relevant. Examples of implementation of these techniques are analyzed, the most illustrative of which is the tool for assessing inventions ‘VentureQuest’, adapted by the Technology Transfer Office of Kansas University Medical Center to the needs of the relevant medical college, which provides objective, pragmatic feedback, identifying strengths and weaknesses to reduce risk and achieve tremendous success in commercialization.

The study does not cover all aspects of the outlined problem. As for further research, there will be a comparison of the innovation scientific activity of medical colleges at U.S. Universities and medical education establishments of the European Union.

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